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## **REMARKS**

The Office Action dated April 23, 2003 has been carefully reviewed. Claims 1-56 are pending in this patent application. By this amendment, claims 1, 5, 6, 11, 14, 17, 20, 21, 24, 25, 28, 29, 30, 34, 36, 38, 39, 43, 45, 47, 49, 51, 53, 54, 55, and 56 have been amended. Reconsideration of this application, as amended, is respectfully requested.

### **35 U.S.C. § 112 Rejection**

Claim 56 was rejected under 35 U.S.C. § 112 as being indefinite. Claim 56 has been amended to correct the antecedent basis problem pointed out by the Examiner. As amended, claim 56 is believed to comply with 35 U.S.C. § 112.

### **35 U.S.C. § 102 Rejection (Farey)**

Claims 45-56 were rejected under 35 U.S.C. § 102(e) as being anticipated by Farey (U.S. Patent No. 6,203,575). Claims 45, 47, 49, 51, 53, 54, 55, and 56 have been amended to more clearly define the invention. Reconsideration of claims 45-56, as amended, is respectfully requested.

### **Discussion Re: Patentability of Claim 45**

#### ***Amended Claim 45***

Among other limitations, amended claim 45 recites the following:

positioning said trial assembly in a scale mechanism having a plurality of distinct values displayed thereon whereby said trial offset indicia of said trial head

portion aligns with one of said plurality of distinct values displayed on said scale mechanism;

securing a final head portion to a final body portion based on said one of said plurality of distinct values so as to form a final prosthesis assembly.

Farey does not disclose a scale mechanism having a plurality of distinct values displayed thereon, much less, positioning a trial assembly in the scale mechanism such that a trial offset indicia of a head member of the trial assembly aligns with one of the distinct values displayed on the scale mechanism as claimed in amended claim 45. It is axiomatic that anticipation of a claim under 35 U.S.C. § 102 is proper only if the prior art reference discloses each and every element of the claim. Since Farey does not disclose each and every element of Applicants' amended claim 45, Farey does not anticipate Applicants' claim 45.

#### Discussion Re: Patentability of Claim 46

Claim 46 depends directly from claim 45. As a result, claim 46 is allowable for, at least, the reasons hereinbefore discussed with regard to claim 45.

#### Discussion Re: Patentability of Claim 47

The discussion regarding the patentability of claim 45 is relevant to the patentability of claim 47. As a result, claim 47 is allowable over the cited art.

#### Discussion Re: Patentability of Claim 48

Claim 48 depends directly from claim 47. As a result, claim 48 is allowable for, at least, the reasons hereinbefore discussed with regard to claim 47.

#### Discussion Re: Patentability of Claim 49

##### *Amended Claim 49*

Among other limitations, amended claim 49 recites the following:

a trial assembly including a trial body portion having a trial body mating component, and a trial head portion having (i) *a trial head member which includes a trial offset indicia defined in a first bearing surface thereof*, and (ii) an eccentrically located trial head mating component, said trial head mating component being configured to mate with said trial body mating component; and

a final prosthesis assembly including a final body portion having a final body mating component, and a final head portion having (i) *a final head member which includes a final offset indicia positioned on a second bearing surface thereof*, and (ii) an eccentrically located final head mating component, said final head mating component being configured to mate with said final body mating component. (Emphasis added.)

Farey does not disclose a trial head member which includes a trial offset indicia *defined in a first bearing surface thereof*, or a final head member which includes a final offset indicia *positioned on a second bearing surface thereof* as claimed in amended claim 49. Rather, Farey's "marking", which appears to correspond to "the direction of displacement 45" (see Farey at column 4, lines 63-65), is defined by structure located on the underneath side of the prosthesis head 4 as shown in Fig. 4b of Farey. This structure is clearly spaced apart from the bearing surface of the prosthesis head 4. It is axiomatic that anticipation of a claim under 35 U.S.C. § 102 is proper only if the prior art reference discloses

each and every element of the claim. Since Farey does not disclose each and every element of Applicants' amended claim 49, Farey does not anticipate Applicants' claim 49.

#### Discussion Re: Patentability of Claim 50

Claim 50 depends directly from claim 49. As a result, claim 50 is allowable for, at least, the reasons hereinbefore discussed with regard to claim 49.

#### Discussion Re: Patentability of Claim 51

The discussion regarding the patentability of claim 49 is relevant to the patentability of claim 51. As a result, claim 51 is allowable over the cited art.

#### Discussion Re: Patentability of Claim 52

Claim 52 depends directly from claim 51. As a result, claim 52 is allowable for, at least, the reasons hereinbefore discussed with regard to claim 51.

#### Discussion Re: Patentability of Claim 53

The discussion regarding the patentability of claim 45 is relevant to the patentability of claim 53. As a result, claim 53 is allowable over the cited art.

#### Discussion Re: Patentability of Claim 54

The discussion regarding the patentability of claim 45 is relevant to the patentability of claim 54. As a result, claim 54 is allowable over the cited art.

#### Discussion Re: Patentability of Claim 55

The discussion regarding the patentability of claim 49 is relevant to the patentability of claim 55. As a result, claim 55 is allowable over the cited art.

#### Discussion Re: Patentability of Claim 56

The discussion regarding the patentability of claim 45 is relevant to the patentability of claim 56. As a result, claim 56 is allowable over the cited art.

#### **35 U.S.C. § 102 Rejection (Hartdegen)**

Claims 1-2, 4-5, 9-10, 16-17, 19-20, 24, 27-28, 32-33, 35-37, 41-42, and 44-56 were rejected under 35 U.S.C. § 102(e) as being anticipated by Hartdegen et al. (Pub. No. US 2001/0053935). Reconsideration of this rejection is respectfully requested.

Note that the present application (i.e. 09/904,752) claims the benefit of U.S. provisional application serial no. 60/221,657, filed July 28, 2000, a copy of which is attached hereto as ATTACHMENT. All of the pending claims are supported by this provisional application. The Examiner appears to rely on a provisional application (i.e. 60/201,503) of which Hartdegen et al. is a published non-provisional application for a filing date pre-dating the July 28, 2000 priority

date afforded the pending patent application. However, the Examiner has not demonstrated that the subject matter on which the Examiner relies to support her § 102(e) rejection was “described” in the provisional application. (See 35 U.S.C. § 102(e)). Applicants respectfully request that the Examiner demonstrate that the subject matter on which the Examiner relies to support her § 102(e) rejection was “described” in the provisional application. In any event, no such “description” has heretofore been produced. Thus, it has not been established that Hartdegen anticipates any of claims 1-2, 4-5, 9-10, 16-17, 19-20, 24, 27-28, 32-33, 35-37, 41-42, and 44-56. Accordingly, withdrawal of this rejection is respectfully requested.

### **35 U.S.C. § 103 Rejection (Farey)**

Claims 1-2, 4-5, 7-17, 19-20, 22-29, 32-38, 41-44 were rejected under 35 U.S.C. § 103 as being unpatentable over Farey (U.S. Patent No. 6,203,575). Claims 1, 5, 11, 14, 17, 20, 24, 25, 29, and 38 have been amended to more clearly define the invention. Reconsideration of claims 1-2, 4-5, 7-17, 19-20, 22-29, 32-38, 41-44, as amended, is respectfully requested.

### **Discussion Re: Patentability of Claim 1**

#### ***Amended Claim 1***

Among other limitations, amended claim 1 recites the following:

positioning said trial assembly in a scale mechanism having a plurality of distinct values displayed thereon whereby said trial offset indicia of said trial head portion aligns with one of said plurality of distinct values displayed on said scale mechanism;

securing a final head portion to a final body portion based on said one of said plurality of distinct values so as to form a final prosthesis assembly.

As discussed above, Farey does not disclose a scale mechanism having a plurality of distinct values displayed thereon, much less, positioning a trial assembly in the scale mechanism such that a trial offset indicia of a head member of the trial assembly aligns with one of the distinct values displayed on the scale mechanism as claimed in amended claim 45. Thus, modifying Farey as proposed in the 4/23/03 Office Action does not arrive at the invention of amended claim 1. Accordingly, the proposed modification of Farey does not establish a prima facie case of obviousness under 35 U.S.C. § 103 with regard to the invention of amended claim 1.

#### Discussion Re: Patentability of Claim 2, 4-5, and 7-16

Each of claims 2, 4-5, and 7-16 depends directly or indirectly from amended claim 1. As a result, each of claims 2, 4-5, and 7-16 is allowable for the reasons hereinbefore discussed with regard to amended claim 1.

#### Discussion Re: Patentability of Claim 17

The discussion regarding the patentability of claim 1 is relevant to the patentability of claim 17. As a result, claim 17 is allowable over the cited art.



### Discussion Re: Patentability of Claim 19-20 and 22-27

Each of claims 19-20 and 22-27 depends directly or indirectly from amended claim 1. As a result, each of claims 19-20 and 22-27 is allowable for the reasons hereinbefore discussed with regard to amended claim 17.

### Discussion Re: Patentability of Claim 28

#### *Amended Claim 28*

Among other limitations, amended claim 28 recites the following:

a trial assembly including a trial body portion having a trial bore defined therein, and a trial head portion having (i) a trial head member which includes a trial offset indicia defined in a first bearing surface thereof, and (ii) an eccentrically located trial stem extending from said trial head member, said trial head stem being configured to be received within said trial bore; and

a final prosthesis assembly including a final body portion having a final bore defined therein, and a final head portion having (i) a final head member which includes a final offset indicia positioned on a second bearing surface thereof, and (ii) an eccentrically located final head stem extending from said final head portion, said final head stem being configured to be received within said final bore.

As discussed above, Farey does not disclose a trial head member which includes a trial offset indicia *defined in a first bearing surface thereof*, or a final head member which includes a final offset indicia *positioned on a second bearing surface thereof* as claimed in amended claim 28. Rather, Farey's "marking", which appears to correspond to "the direction of displacement 45" (see Farey at column 4, lines 63-65), is defined by structure located on the underneath side of the prosthesis head 4 as shown in Fig. 4b. This structure is clearly spaced apart from the bearing surface of the prosthesis head 4. Thus, modifying Farey as proposed in the 4/23/03 Office Action does not arrive at the

invention of amended claim 28. Accordingly, the proposed modification of Farey does not establish a prima facie case of obviousness under 35 U.S.C. § 103 with regard to the invention of amended claim 28.

Discussion Re: Patentability of Claim 29 and 32-35

Each of claims 29 and 32-35 depends directly or indirectly from amended claim 28. As a result, each of claims 29 and 32-35 is allowable for the reasons hereinbefore discussed with regard to amended claim 28.

Discussion Re: Patentability of Claim 36

The discussion regarding the patentability of claim 28 is relevant to the patentability of claim 36. As a result, claim 36 is allowable over the cited art.

Discussion Re: Patentability of Claim 37-38 and 41-44

Each of claims 37-38 and 41-44 depends directly or indirectly from amended claim 36. As a result, each of claims 37-38 and 41-44 is allowable for the reasons hereinbefore discussed with regard to amended claim 36.

**35 U.S.C. § 103 Rejection (Farey/Leonard)**

Claims 3-4, 18-19, 31, 33, 40, and 42 were rejected under 35 U.S.C. § 103 as being unpatentable over Farey (U.S. Patent No. 6,203,575) in view of Leonard (U.S. Patent No. 6,228,120). Reconsideration of claims 3-4, 18-19, 31, 33, 40, and 42 is respectfully requested.

Discussion Re: Patentability of Claim 3-4

Each of claims 3-4 depends directly or indirectly from amended claim 1. As a result, each of claims 3-4 is allowable for the reasons hereinbefore discussed with regard to amended claim 1.

Discussion Re: Patentability of Claim 18-19

Each of claims 18-19 depends directly or indirectly from amended claim 17. As a result, each of claims 18-19 is allowable for the reasons hereinbefore discussed with regard to amended claim 17.

Discussion Re: Patentability of Claim 31, 33, 40, and 42

Each of claims 31, 33, 40, and 42 depends directly or indirectly from amended claim 28. As a result, each of claims 31, 33, 40, and 42 is allowable for the reasons hereinbefore discussed with regard to amended claim 28.

**35 U.S.C. § 103 Rejection (Hartdegen/Leonard)**

Claims 3-4, 18-19, 31, 33, 40, and 42 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hartdegen et al. (Pub. No. US 2001/0053935) in view of Leonard et al. (U.S. Patent No. 6,228,120).

Again, the Examiner appears to rely on a provisional application (i.e. 60/201,503) of which Hartdegen et al. is a published non-provisional application for a filing date pre-dating the July 28, 2000 priority date afforded the pending

patent application. However, the Examiner has not demonstrated that the subject matter on which the Examiner relies to support her § 103(a) rejection was "described" in the provisional application (See 35 U.S.C. § 102(e)).

Applicants respectfully request that the Examiner demonstrate that the subject matter on which the Examiner relies to support her § 103(a) rejection was "described" in the provisional application. In any event, no such "description" has heretofore been produced. Thus, a prima facie case of obviousness has not been established with regard to any of claims 3-4, 18-19, 31, 33, 40, and 42. Accordingly, withdrawal of this rejection is respectfully requested.

#### **Claims 30 and 39**

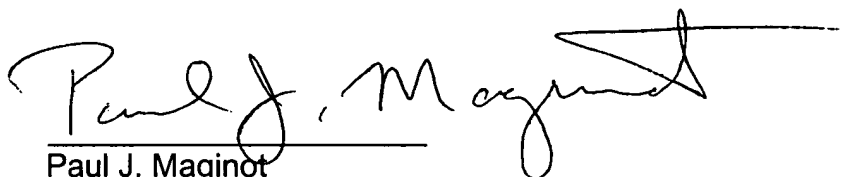
Claims 30 and 39 do not appear to have been rejected over any prior art. Allowance of these claims is respectfully requested.

## Conclusion

In view of the foregoing amendments and remarks, it is submitted that this application is in condition for allowance. Action to that end is hereby solicited.

Respectfully submitted,

MAGINOT, MOORE & BECK

A handwritten signature in black ink, appearing to read "Paul J. Maginot", with a long horizontal line extending from the end of the signature.

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## DEVICE AND METHOD FOR POSITIONING AN ECCENTRIC HUMERAL HEAD OF A HUMERUS PROTHESIS FOR A SHOULDER ARTHROPLASTY

### Field of the Invention

The present invention relates to prostheses for reconstructive surgery of a gleno-humeral joint and, more particularly, to the positioning of an eccentric head of a humerus prostheses for reconstructive surgery of a gleno-humeral joint.

### Background

In total shoulder arthroplasty, reproduction of the correct location of the humeral articular surface is critical to reestablishing joint biometrics. Translating this location to the implant is thus of critical importance.

Each shoulder arthroplasty needs to be adapted to the patient's unique combination of soft tissue and bone anatomy. As well, the patient typically has high expectations of the function and durability of the arthroplasty. Thus, the implant and the implant technique must be precise.

In view of this, there has been developed a range of prostheses designed to fit the various sizes and shapes of people's anatomy. For shoulder arthroplasty, a prosthesis with a humerus head has been developed. It has been recognized, though, that the humerus head may need to be eccentrically mounted relative to the prosthesis body in order to cover the exposed, resected humerus head. There has been a problem, however, with the ability to adequately position the eccentric head on the implant in order to meet the needs

of every patient. Typically, the eccentric head is positionable in only a few select orientations relative to the eccentricity.

Thus, there is a need for an prosthetic implant that can utilize an eccentric head wherein the eccentric head may be positioned in any number of rotatably eccentric positions.

### Summary of the Invention

The present invention is a method, apparatus and corresponding implant for positioning an eccentric head on a trial implant/broach and transferring or translating the eccentric position of the head onto the actual or definitive implant. The present invention allows the eccentric head to be positioned in an infinite amount of positions or orientations to best reproduce the articular geometry of the patient. The infinite dialability is optimum for reconstruction purposes.

Because each shoulder arthroplasty needs to be adapted to the patient's unique combination of soft tissue and bone anatomy, the present system maximizes the surgeon's flexibility in matching a wide variety of anatomic requirements. The present invention places a premium on secure fixation, conservation of bone and optimization of mechanics.

During the trialing process, the humeral head trial is lockable into one of an infinite variety of rotational positions (a set orientation) that then may be transferred to the definitive humeral head of the definitive implant. A means is provided for locking the eccentric trial head to the trial/broach in a set orientation that allows for the trialing process to occur without spinning of the eccentric trial

head in the broach taper. In one form, this is accomplished via a captured screw in the eccentric trial head that extends beyond the taper of a neck of the eccentric trial head. The captured screw engages threads in a bottom of a bore in a taper in the broach.

Once the eccentric head has been threaded onto the trial broach, it is rotated into a correct position covering the resected humeral head surface. The eccentric head may be rotated into an infinite number of positions on the trial broach without having to be locked in any particular orientation. Once the eccentric head is in position, the captured screw is tightened or locked. Trial reduction is carried out and if deemed satisfactory, the broach/eccentric head trial head assembly (or trial assembly) is removed as a one piece unit from the humerus of the patient.

In accordance with an aspect of the present invention, the eccentric head includes a mark or indicia showing the position of maximum offset. Once the trial assembly has been removed, from the patient's humerus, it is placed in an impaction stand or block. The impaction stand allows the measurement of the orientation of the eccentric head (by the indicia) on the trial broach, and the translation or transference of that orientation onto the definitive implant. The impaction stand has a scale or demarcations on a surface thereof. The orientation of the indicia of the eccentric head is noted relative to the scale.

The trial assembly is then removed from the impaction stand and the appropriate size of the definitive implant is placed in the impaction stand. An appropriate size of definitive eccentric head is placed on the definitive implant.



The definitive eccentric head includes an indicia either as an etched or otherwise arrow or other marking on the nonarticulating surface (or by a removable sticker or the like on the articulating surface) showing the position of maximum offset (in like manner to the trial eccentric head). The indicia of the definitive eccentric head is orientated or aligned with the scale to the same number or marking as the trial eccentric head.

Once the definitive eccentric head has been properly aligned, the definitive eccentric humeral head is impacted into place onto the definitive implant while on the impaction stand. In this manner, the appropriate position of the humeral head for the definitive implant has been successfully transferred from the trial assembly.

It can be appreciated from the foregoing, that the eccentric head may be rotationally positioned in an infinite number of positions, both during trialing and during the final implant.

#### Brief Description of the Drawings

The above-mentioned and other features and advantages of this invention, and the manner of attaining them, will become more apparent and the invention will be better understood by reference to the following description of an embodiment of the invention taken in conjunction with the accompanying drawings, wherein:

Figs. 1A and 1B are elevational views of exemplary humerus prostheses/trail broach bodies used in conjunction with the eccentric head of the present invention;

Fig. 2 is an enlarged, side sectional view of a partial humerus with a portion of the humerus head resected (removed) and a trail broach inserted into the glenoid thereof;

Fig. 3 is a bottom plan view of an eccentric trail humerus head;

Fig. 4 is a side elevational view of the eccentric trial humerus head of Fig. 3;

Fig. 5 is a front elevational view of a partial humerus with the humerus head resected;

Fig. 6 is a front elevational view of the partial humerus of Fig. 5 showing a trial standard humerus head that exposes a portion of the surface of the resected humerus head;

Fig. 7 is a front elevational view of the partial humerus of Fig. 5 showing the trial eccentric humerus head covering the surface of the resected humerus head;

Fig. 8 is an enlarged side elevational view of the trial eccentric humerus head of Figs. 3 and 4 having a seating screw extending therefrom;

Fig. 9 is an enlarged perspective view of the seating screw of Fig. 8;

Fig. 10 is a perspective view of a trial eccentric head being attached to the trial broach via a driver;

Fig. 11 is an enlarged, side sectional view of a partial humerus with the trial assembly (broach and eccentric head inserted into the glenoid of the humerus;

Fig. 12 is a top perspective view of an impaction stand;

Fig. 13 is a bottom perspective view of the impaction stand of Fig. 12;

Fig. 14 is a side elevational view of the impaction stand of Figs. 12 and 13;

Fig. 15 is a top plan view of the impaction stand of Figs. 12-14;

Fig. 16 is a bottom plan view of the impaction stand of Figs. 12-14;

Fig. 17 is a perspective view of the impaction stand with a broach or implant seated thereon;

Fig. 18 is an enlarged top plan view of a trial assembly seated on the impaction stand with the indicia (notch) of the trial eccentric head positioned at "5"; and

Fig. 19 is a perspective view of the impaction stand with a definitive implant seated thereon with a definitive eccentric humerus head ready to be impacted onto the implant.

Corresponding reference characters indicate corresponding parts throughout the several views.

#### Detailed Description

With reference to Fig. 1A, there is shown an exemplary, 210mm humerus prosthesis or trial broach generally designated 20. The humerus prostheses/trial

broach 20 includes a stem 22 extending from a neck 24. The neck 24 terminates in a generally flat surface 26 that is adapted to be seated on a surface of a resected humerus head of a patient's humerus. In fig. 1B, there is shown an exemplary, 138mm humerus prosthesis or trial broach generally designated 28. The humerus prostheses/trial broach 28 includes a stem 30 extending from a neck 32. The neck 32 terminates in a generally flat surface 34 that is adapted to be seated on a surface of a resected humerus head of a patient's humerus.

In Fig. 2, there is shown a patient's humerus 36 wherein the humerus head 38 has been resected in accordance with standard shoulder arthroplasty surgery. It is beyond the scope of the present invention to discuss humerus head resection. Various texts and papers may be consulted for this procedure. After the humerus head 38 has been resected, the humerus head must be sized for a prosthetic head of the implant. Various sizes are available such as 44, 48 and 52mm. It will be assumed that an eccentric head will be chosen. In Fig. 2, the medullary canal of the humerus 36 has been reamed and the trial broach 20 has been placed thereon. The flat 26 is in contact with a surface 40 of the resected humerus head 38. The trial broach 20 is ready to be fitted with a trial eccentric head.

Preoperative evaluation of the Humerus 36 with templates (not shown) helps determine the size of the prostheses and level of humerus head resection. Humeral head resection is accomplished as is known in the art or with other

methods the detail of which is beyond the scope of the present invention and this disclosure.

Briefly, in Figs. 5-7 there is shown a reason for selecting an eccentric head. Fig. 5 shows the humerus 36 whose humerus head 38 has been resected. It is now necessary to find a trial head that will cover the humerus surface 40 formed by the resection. In Fig. 6 a trial standard head 60 having a tapered stem 62 is shown in position over the surface 40. It can be seen that the surface 40 is visible around the periphery of the trial standard head 60. A centerline shows how the trial standard head 60 fits over the surface 40. Even with rotation of the trial standard head 60, the surface 40 is exposed. Thus, the trial standard head 60 is not appropriate. In Fig. 7, a trial eccentric head 42 having a tapered stem 46 is shown in position over the surface 40. It can be seen that with the correct rotation/orientation/placement of the trial eccentric head 42, the entire surface 40 is covered. With an infinite number of rotational positions, an eccentric head is thus appropriate.

Referring to Figs. 3, and 4, a trial eccentric head 42 in accordance with the principles of the present invention is shown. Four eccentric head 42 sizes may be provided, 44mm, 48mm, 52mm, and 56mm. The trial eccentric head 42 includes a tapered stem 46 that is positioned off center (approximately a 4mm offset) such that an eccentricity during rotation thereabout is defined or formed. The stem 46 extends essentially perpendicularly from a bottom surface 43 of the trial eccentric head 42 and includes a bore 46 that extends through the stem 42 and the head 42. The trial eccentric head 42 includes an indicia (here a notch)

44 that indicates a maximum offset position for the eccentric head 42. It should be appreciated that other types of indicia may be used. Here the notch 44 is located on the edge of the articular surface of the eccentric head 42.

Referring to Fig. 9, a retaining screw or the like 50 for the trial assembly (trial eccentric head and trial broach) is shown. The retaining screw 50 includes a head 52 having an opening 54 for receiving a screw driver or the like. The opening may be hex shape or otherwise. Extending from the head 52 is a shank 56 terminating in threads 58. The retaining screw 50 is designed to fit into the bore 48 of the trial eccentric head 42 with its threads 58 extending therefrom (see Fig. 8).

Referring to Fig. 10, the trial broach 20 is shown wherein the trial eccentric head 42 is ready to be attached thereto. Using an appropriate screw driver 66, the eccentric trial head 42 is attached to the trial broach by threading the screw 50 into a complementary threaded bore 64 in the flat 26. Once the eccentric head 42 is attached to the trial broach 20 it is inserted into the glenoid of the humerus 36 (see Fig. 11). Once the trial prosthesis is in place as depicted in Fig. 11, the screw 50 may be loosened to rotate the eccentric head 42 to a proper orientation. Once a proper rotational orientation has been achieved, the screw 50 is tightened. The trial prosthesis may now be removed from the humerus 36. Once the trial prosthesis has been removed from the humerus 36 it is ready to be place in an impaction stand or block in accordance with the principles of the present invention. The position of the eccentric head 42 is now

ready to be transferred or reproduced in the final or definitive prosthetic implant that will remain in the patient.

Referring to Figs. 12-16, there is shown an impaction stand or block generally designated 70 in accordance with the principles of the present invention. The impaction stand 70 may be made of a suitable plastic or the like and is essentially a hexagonal cylinder. The impaction stand 70 is designed to accommodate various sizes of trial broaches/final prostheses. To this end, the impaction stand 70 has two faces or surfaces 76 and 78 on opposite sides thereof. Extending diagonally from the surface 76 to an outside surface of the cylinder is a first channel 72. Extending diagonally from the surface 78, opposite in orientation to the first channel 72, is a second channel 74. The second channel 74 extends to an outside surface of the cylinder. The first and second channels 72 and 74 and their respective surfaces 76 and 78, are designed to accommodate various sizes of trial broaches/final prostheses. In the figures, surface 76/channel 72 is designed to hold trial broaches/final prostheses of sizes 6mm, 8,, and 10mm, while the surface 78/channel 74 is designed to hold trial broaches/final prostheses of sizes 12mm, 14mm, and 16mm. Of course, it should be appreciated that the impaction block 70 may be designed for other sizes, or several blocks for the various sizes.

Each surface 76 and 78 includes an indicia or scale in the manner of a clock or the like that divides the periphery thereof into sections. The scale is used to reference the position of the notch 44 of the trial eccentric head 42 when

the trial assembly is place in the impaction stand (as well as the final assembly as indicated below).

Referring to Figs. 17 and 18 the trial assembly is placed into the impaction stand 70 (in Fig. 17, the eccentric head is not present to illustrate how the body 22 fits in the impaction stand 70/channel 74). As seen in Fig. 18 the position of the notch 44 in the trial eccentric head 42 is noted (here at position 5) for transference or reproduction onto the final prosthesis.

The final step is to fit the final eccentric head onto the final humeral stem (of the same size as the trial broach). The trial assembly is removed from the impaction stand 70 and the final humeral stem/body is placed therein (see Fig. 17). In Fig. 19, a final eccentric head 80 is chosen of the same size as the trial eccentric head 42. The final eccentric head 80 is held by an impactor 86 such as a Delrin-tipped impactor. The final eccentric head includes an indicia, either as a permanent mark or the like on the nonarticulating surface thereof or as a removable sticker or the like on the articulating surface thereof, that indicates the maximum offset in like manner to the trial eccentric head 42. The indicia of the final eccentric head 80 is aligned with the marking or indicia on the scale of the surface 78 that is the same as that noted above (here "5"). The taper 82 of the eccentric head 80 is inserted into a complementary tapered bore 84. Keeping the indicia of the eccentric head 80 as noted, the final eccentric head 80 is impacted onto the final humeral stem with a mallet (not shown) onto the impactor 86. The final assembly is now ready to be inserted back into the patient's humerus.



While this invention has been described as having a preferred design and/or configuration, the present invention can be further modified within the spirit and scope of this disclosure. This application is therefore intended to cover any variations, uses, or adaptations of the invention using its general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which this invention pertains.



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## CLAIMS

### WHAT IS CLAIMED IS:

1. A trial prosthesis for a shoulder arthroplasty comprising:

a trial broach having a stem, neck and flat, the flat including a threaded bore;

an eccentric head having an offset indicia, a tapered stem, and a bore through said eccentric head and said stem, said eccentric head adapted to be received on said flat of said trial broach with said stem in said threaded bore; and

a screw, adapted to extend through said eccentric head bore and allow infinite rotation of said eccentric head in a first mode, and to prevent infinite rotation of said eccentric head in a second mode.

2. A method of positioning an eccentric head on a prosthesis comprising:

placing an eccentric head having an indicia of offset onto a trial broach, the eccentric head adapted to provide infinite rotation on the trial broach in a first mode, and to provide a fixed mode

placing the trial broach and eccentric head into a humerus of a patient;

adjusting the eccentric head as appropriate while the eccentric head is in a first mode;

putting the eccentric head into the second mode;

removing the trial broach and eccentric head from the humerus of a patient;

noting a position of the indicia of the eccentric head on a scale;

placing a final eccentric head having a final indicia onto a final prosthesis on the scale in the same position as the position of the indicia of the eccentric head.

Fig. 1A

Fig. 1B

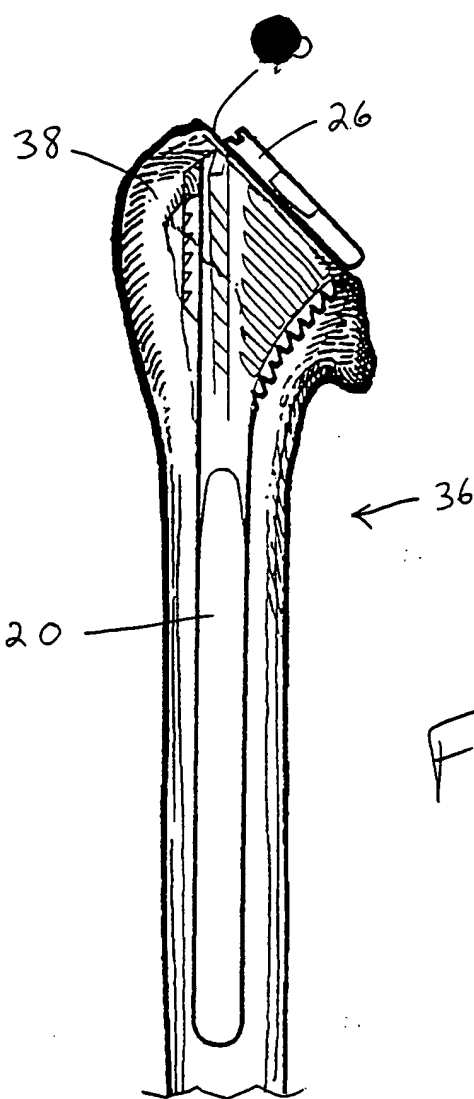
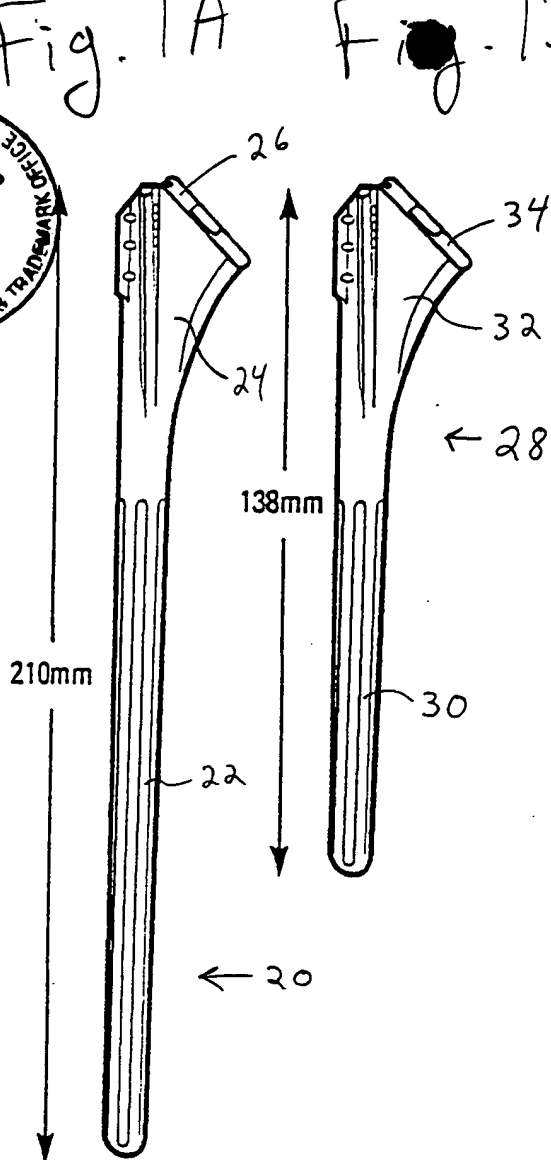
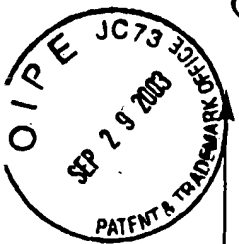


Fig. 2

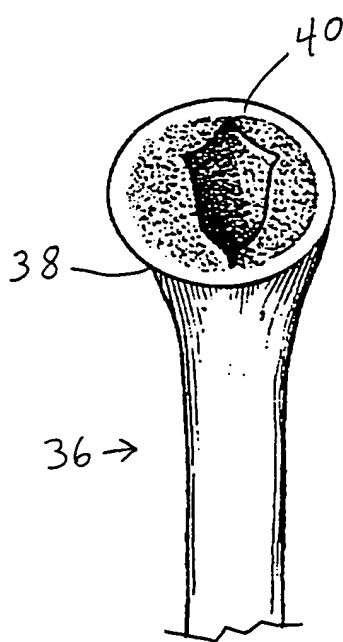


Fig. 5

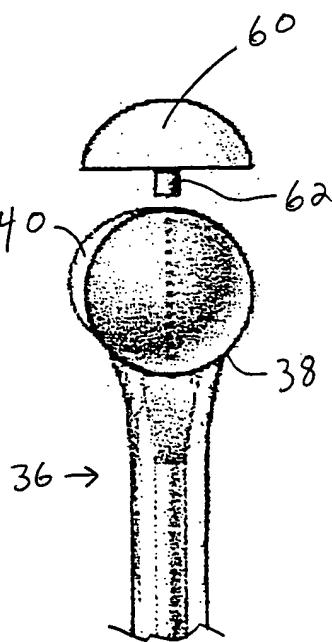


Fig. 6

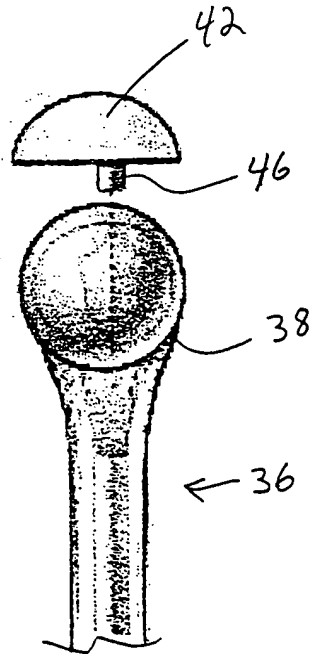


Fig. 7

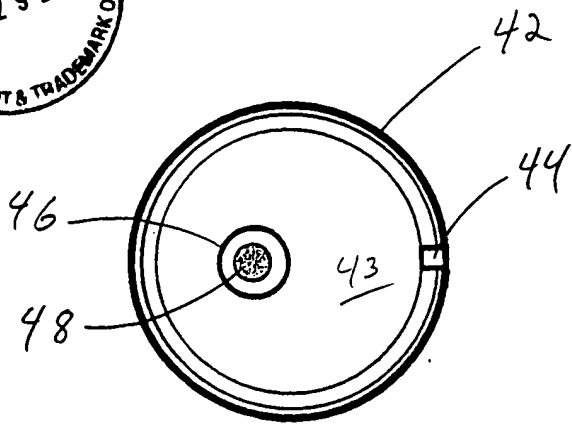


Fig. 3

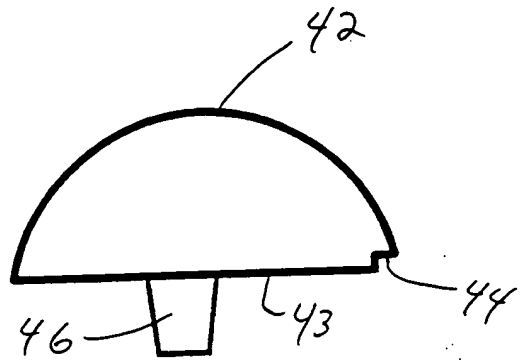


Fig. 4

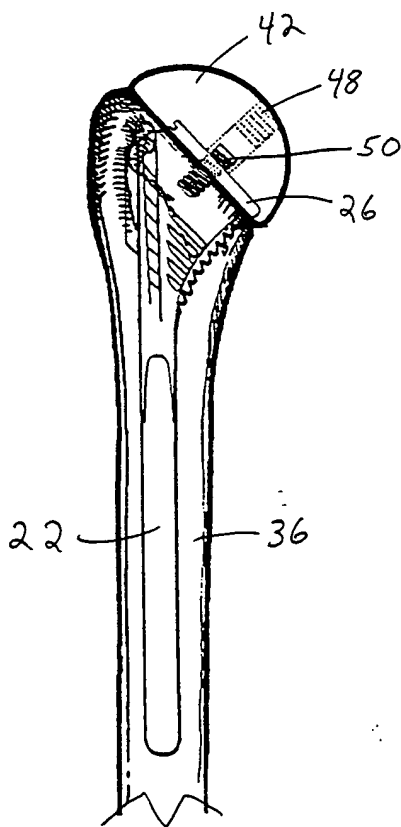


Fig. 11

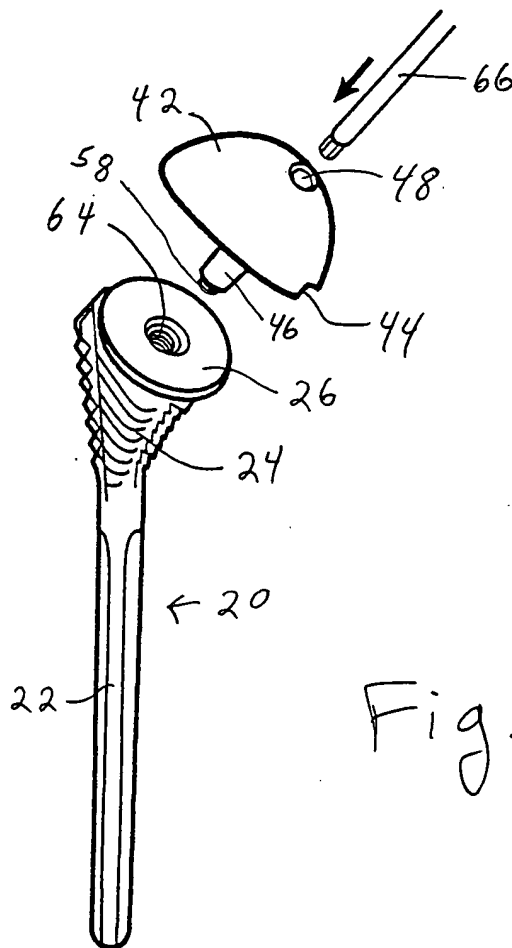


Fig. 10

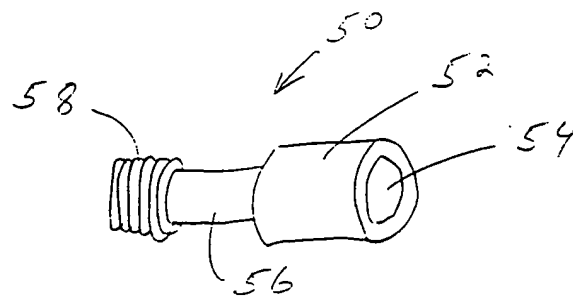
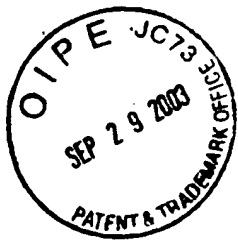


Fig. 9

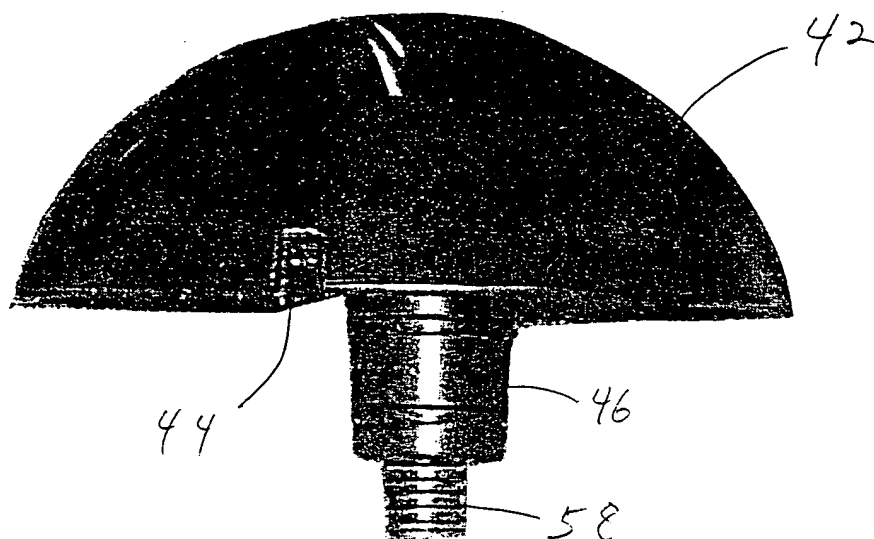


Fig. 8

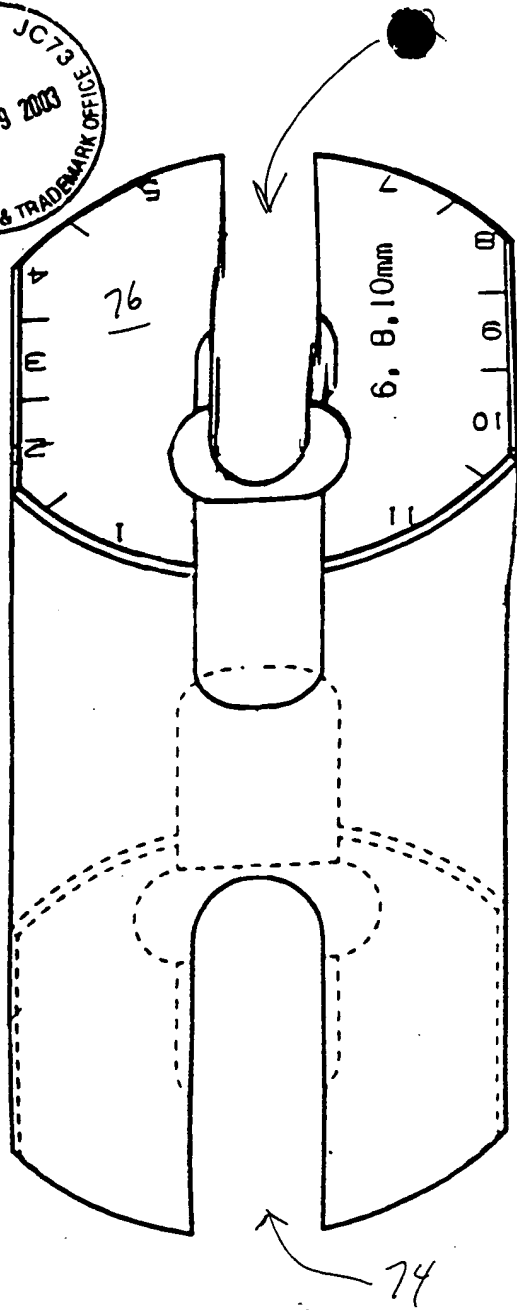


Fig. 12

70  
↙

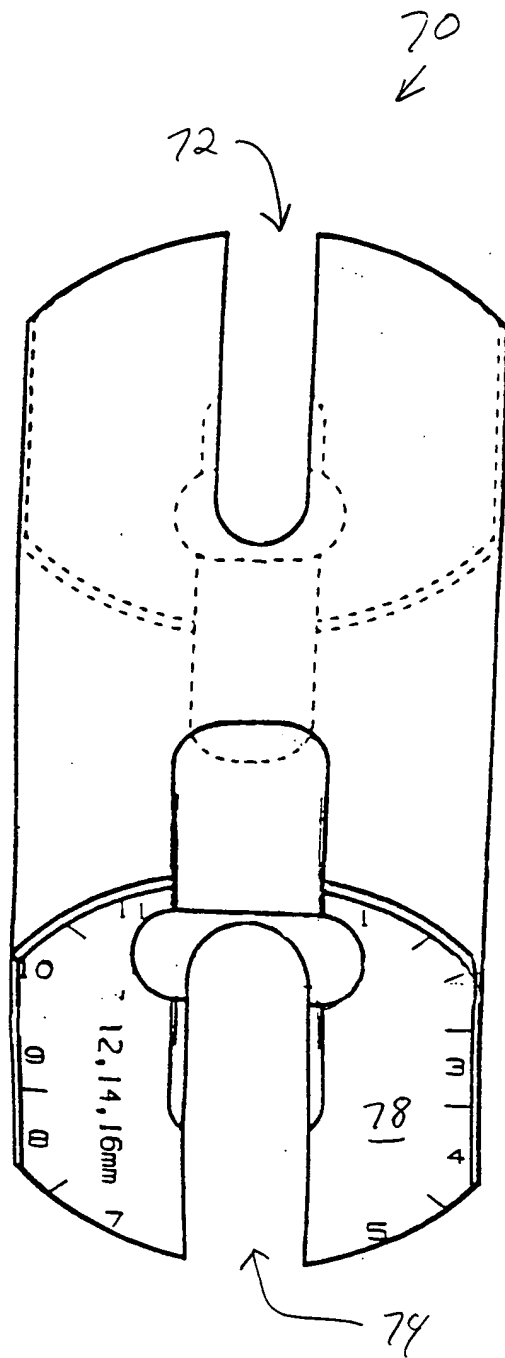


Fig. 13

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Fig. 15

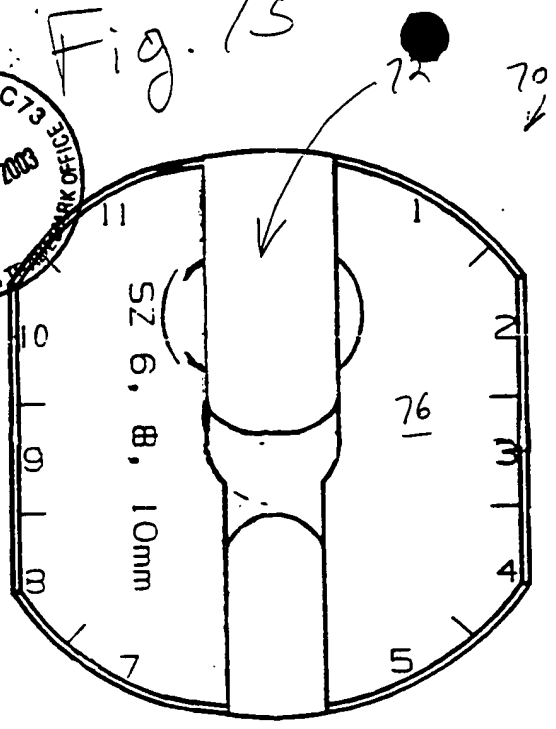


Fig. 16

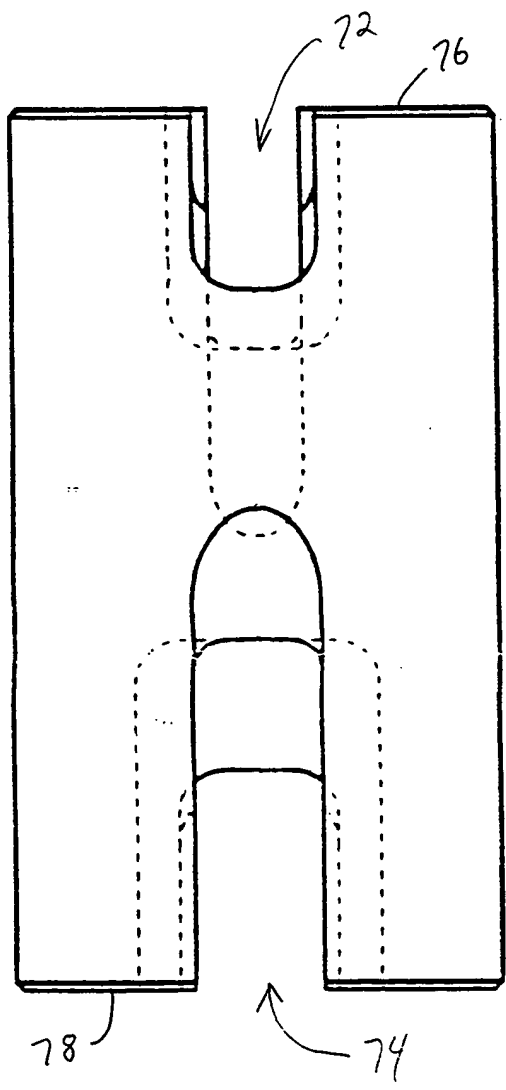
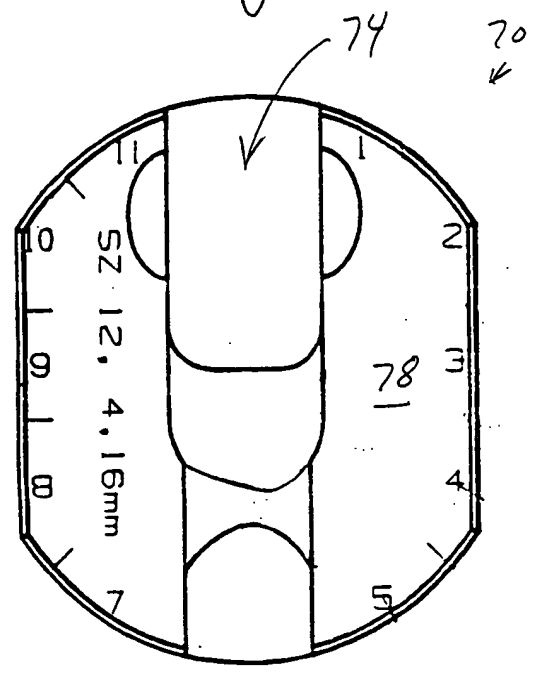


Fig. 14



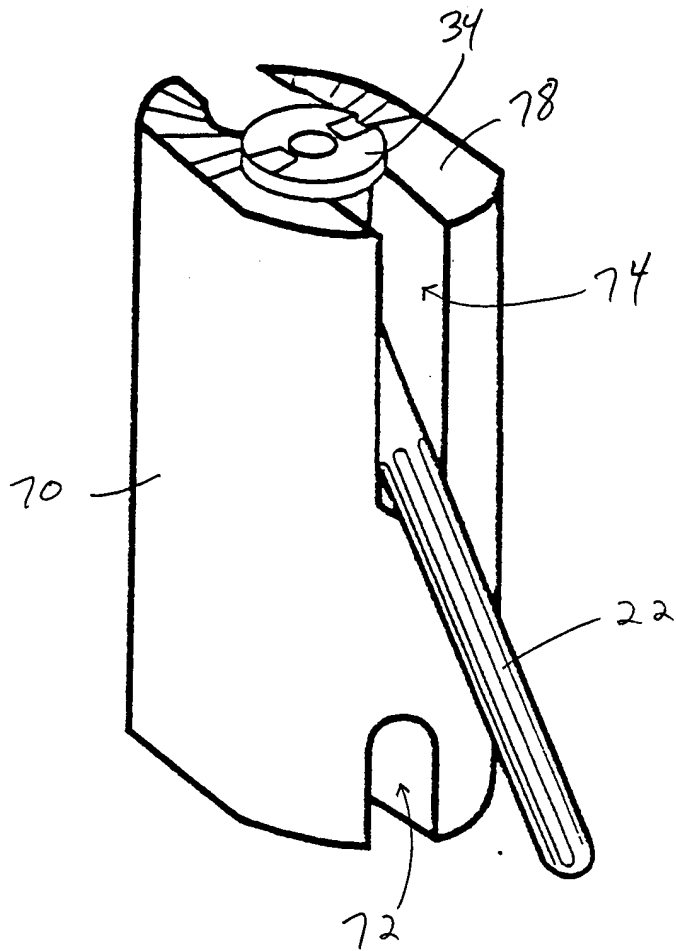


Fig. 17

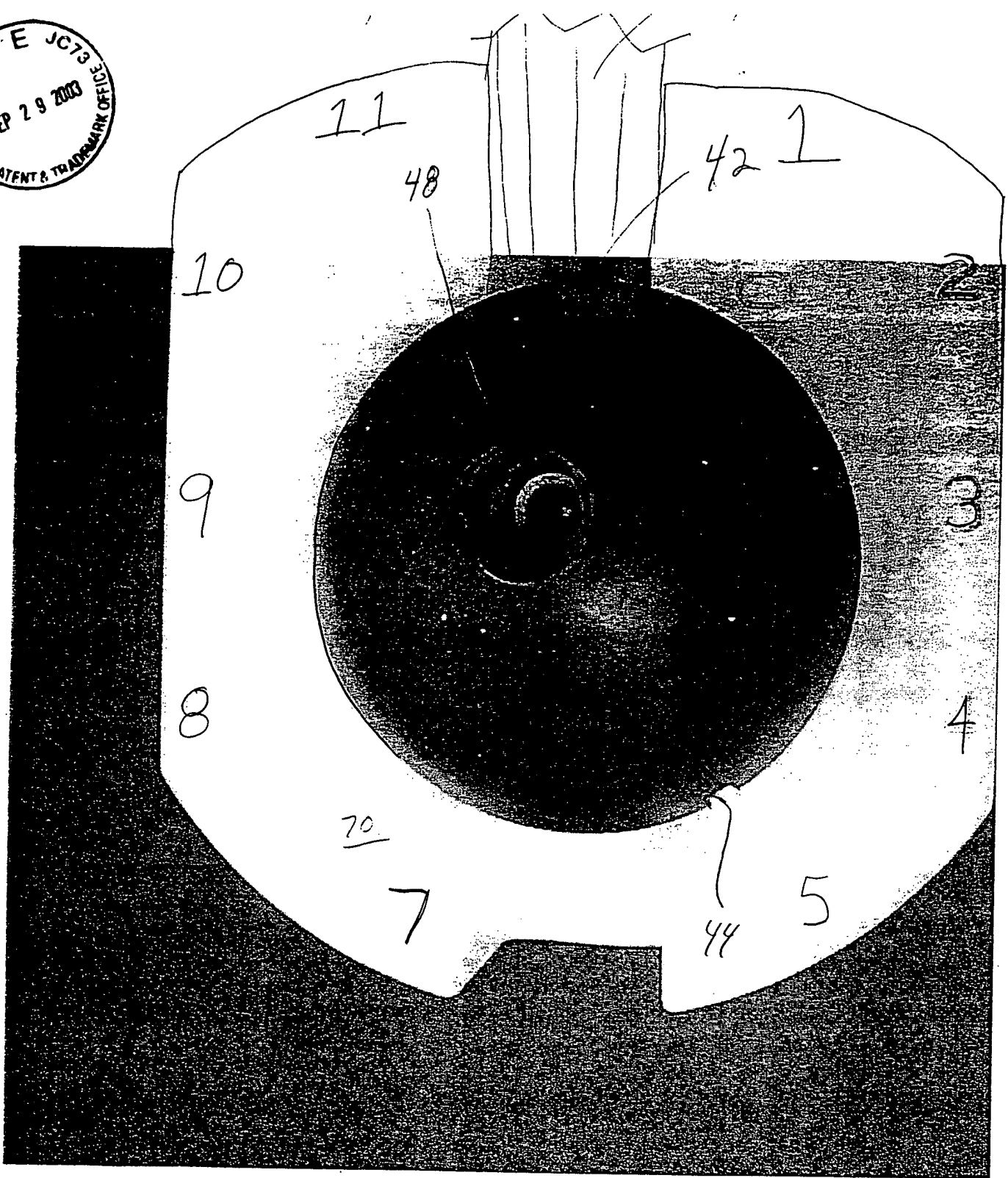


Fig. 18

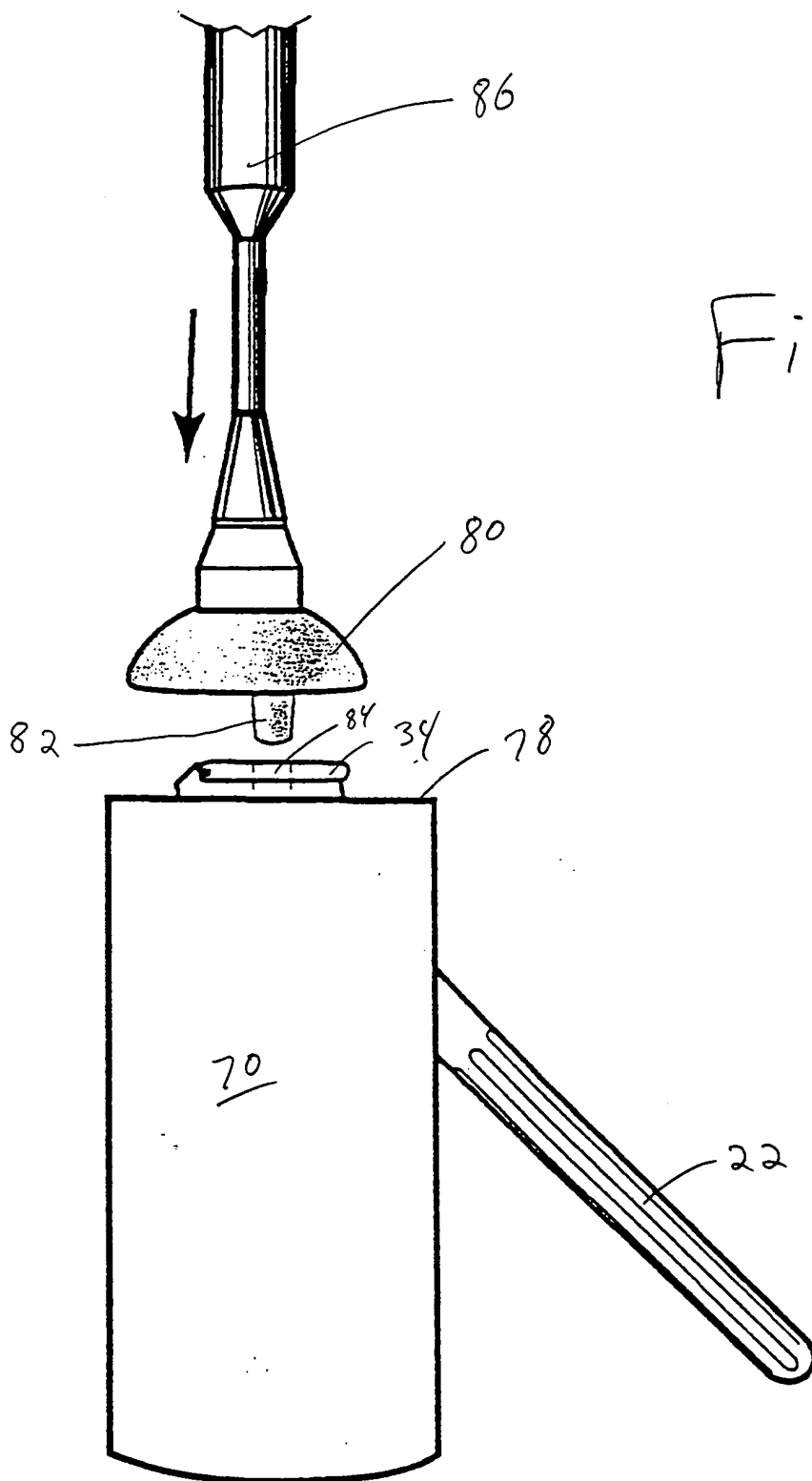
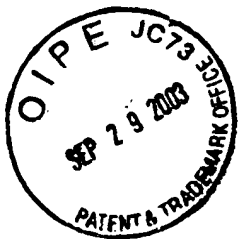


Fig. 19